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Frank S DiGiglio			CARTER, KENDRA D	
Scully Scott Murphy & Presser			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/717,182	Applicant(s) XILINAS ET AL.
	Examiner KENDRA D. CARTER	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 March 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 6.13 and 42-64 is/are pending in the application.
- 4a) Of the above claim(s) 64 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 6.13 and 42-63 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 09/485,909.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/06)
 Paper No./Mail Date 12/23/04.
- 4) Interview Summary (PTO-413)
 Paper No./Mail Date. _____.
- 5) Notice of Informal Patent Application
 6) Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 6, 13 and 42-63, in the reply filed on November 30, 2007 is acknowledged. Further the Applicant elected the following species in the reply filed March 20, 2008: 1) vitamin C as the species of antioxidant; 2) tacrine as the species of acetylcholine enhancers; 3) copper as the species of trace metals; and 4) vitamin B12 as the species of prosthetic groups. The traversal is on the ground(s) that the kit of Group II encompasses numerous embodiments of the compositions of Group I, thus sufficient to rebut the Examiner's finding that Group I and II are independent to warrant restriction. Further, Group I and II both encompass emodiments of pharmaceutical compositions comprising phanquinone and clioquinol. Therefore, Groups I and II are not distinct as they are clearly drawn to be used in a similar manner and to have similar effects in subjects experiencing the symptoms of Alzheimer's disease. This is not found persuasive because the inventions of Group I can be in a kit that does not comprise cliquinol or a vitamin. Claim 6 of Group I discloses that the composition comprises phanquinone and a compound. The compound can be either an antioxidant, acetylcholine enhancer, trace metal, clioquinol, or prosthetic group, where when clioquinol is selected, at least one further compound is selected from the above compounds. Thus, the composition can comprise essentially phanquinone and vitamin A. Further, the composition can be used to treat diarrhea and

not Alzheimer's disease. It is noted that intended use in composition claims do not receive patentable weight.

The requirement is still deemed proper and is therefore made FINAL.

The Examiner would like to note that the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during

prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The Examiner was unable to find the elected species combinations in the art, thus the Examiner searched the genus of the compounds disclosed in claim 6.

Information Disclosure Statement

The information disclosure statement filed December 23, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Particularly, references B02 through B06.

Specification

The disclosure is objected to because of the following informalities: on page 5, line 21, the acetylcholine enhancers are preferable " μ l agonists", which is not recognized in the art.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 1) **Claims 42, 49 and 53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition to treat Alzheimer's disease, does not reasonably provide enablement for a composition to prevent Alzheimer's disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.**

The instant claims are drawn to a composition to treat or prevent Alzheimer's disease. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*,

8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention:

The claim 42 is drawn to "a pharmaceutical composition comprising (a) an amount of phanquinone effective to treat or prevent Alzheimer's disease, and (b) a compound or a mixture of compounds selected from the group comprising antioxidants, acetylcholine enhancers, trace metals, prosthetic groups and clioquinol, provided, when clioquinol is selected, at least one further compound is selected from said group." The claim 49 is drawn to "a pharmaceutical composition comprising (a) an amount of phanquinone effective to treat or prevent Alzheimer's disease, and (b) a mixture of clioquinol and vitamin B₁₂." The claim 53 is drawn to "the a pharmaceutical composition according to claim 49, comprising an amount of clioquinol effective to improve the treatment or prevention of Alzheimer's disease."

(2) The breadth of the claims:

Claims 42, 49 and 53 embraces preventing Alzheimer's disease. This reads on completely preventing Alzheimer's disease. The specification does not enable the composition to prevent Alzheimer's disease.

(3) The state of the prior art:

The state of the art regarding preventing Alzheimer's disease is very low or do not exist. Kedar teaches that in spite of extensive basic and clinical research on Alzheimer's disease, no preventive or long-term effective treatment strategies are available ("Can we prevent Parkinson's and Alzheimer's disease?" J Postgrad Med, 2003, vol. 49, pp. 236-245, see abstract).

(4) The predictability or unpredictability of the art:

The predictability of completely preventing Alzheimer's disease is relatively low. Therefore, to one skilled in the art, prevention of Alzheimer's disease is highly unpredictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high.

(6) The amount of direction or guidance presented / working examples:

In the instant case, the guidance of the specification as to the prevention of Alzheimer's disease with the composition of the invention is completely lacking. The

specification as filed does not speak on or show any working examples any studies performed that prevent all ***. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.02.

(7) The quantity of experimentation necessary:

The instant claims read on preventing Alzheimer's disease. As discussed above the specification fails to provide any support for completely preventing Alzheimer's disease. Applicant fails to provide any information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable.

In conclusion, the applicant is enabled for a composition for treating Alzheimer's disease, but not for a composition for preventing Alzheimer's disease.

- 2) **Claims 6 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Particularly, the term "prosthetic group" is not clear and the specification does not define this term for**

further clarification. For compact prosecution the Examiner searched the elected and claimed prosthetic group, vitamin B12.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6, 42, 43, 44 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by over Chaiyabutr et al. (J Med Ass Thailand, Dec 1985, vol. 68, no. 12, pp. 649-53) as evidenced by .

Chaiyabutr et al. teaches a combination of 600 mg of cliquinol, 60 mg of phanquinone and 6 mg of oxyphenonium bromide (i.e. acetylcholine enhancer) as a treatment of diarrhoeal disease (see title and page 649, column 2, lines 2-6).

In regards to the composition in claim 42 and 43, the Examiner notes that claims 42 and 43 are drawn to the use of the composition to treat or prevent Alzheimer's

disease treat. The intended use does not get patentable weight in composition claims. The claims are only treated on the merits as related to a composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 1) **Claims 13, 45, 48, 49, 53, 54, 57, 58 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chaiyabutr et al. (J Med Ass Thailand, Dec 1985, vol. 68, no. 12, pp. 649-53) as applied to claims 6, 42, 43, 44 and 51 above in view of WHO (The Indian Journal of Pediatrics, July 1989, vol. 56, no. 4, pp. 545-548), and in further view of Alexander et al. (US 4,981,844), in further view of Bissbort et al. (US 5,545,670).**

The teaching of Chaiyabutr et al. is as applied to claims 6, 42, 43, 44 and 51 above.

Chaiyabutr et al. does not teach vitamin B₁₂, C, E or Q10 (claim 13, 45, 48, 49, 54 and 63), or that vitamin B₁₂ is in the amounts of 5 µg to 2mg or 0.5 mg to 1mg (claims 57 and 58).

WHO teaches that vitamins and minerals such as folate, zinc, iron, vitamin B12, vitamin A are involved in intestinal mucosal renewal and/or a variety of immunological responses. Thus, supplementary vitamins and trace elements should be given during persistent diarrhea (see page 547, column 1, last 4, lines to column 2, lines 1-3).

Alexander et al. teaches that the immune response of a patient can be improved by altering the diet of a patient, such as providing vitamin E (see abstract). Other vitamins that should be administered are vitamin C, folic acid, vitamin B12, calcium, and magnesium (see column 3, lines 1-30).

Bissbort et al. teaches a composition to enhance or stimulate the immune response system to combat viral infections and to achieve various other beneficial results (see column 1, lines 6-11). Vitamin B₁₂ is administered between 15-25 µg and 5-50 mg (see column 4, line 32 and column 10, line 14).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the combination of Chaiyabutr et al. and vitamin B₁₂, C, E or Q10 (claim 13, 45, 48, 49, 54 and 63) because of the following teaching: 1)

WHO teaches that supplemental vitamins such as folate, zinc, iron, vitamin B12 and vitamin A should be given during persistent diarrhea; 2) WHO teaches that vitamins involved in a variety of immunological responses should be used; 3) Alexander et al. teaches that the immune response of a patient can be improved by altering the diet of a patient, such as providing vitamin E, vitamin C, folic acid, vitamin B12, calcium, and magnesium (see column 3, lines 1-30 and abstract); and 4) Since both Chaiyabutr et al. and WHO teach treatments for diarrhea, "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992); and *In re Geiger*, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the combination of Chaiyabutr et al. and wherein the amount of vitamin B₁₂ is 5 µg to 2mg or 0.5 mg to 1mg is because Bissbort et al. teaches a composition to enhance or stimulate the immune response system to combat viral infections and to achieve various other beneficial results (see column 1, lines 6-11)

comprises vitamin B₁₂ between 15-25 µg and 5-50 mg (see column 4, line 32 and column 10, line 14).

2) **Claims 50 and 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chaiyabutr et al. (J Med Ass Thailand, Dec 1985, vol. 68, no. 12, pp. 649-53) as applied to claims 6, 42, 43, 44 and 51 above in view of WHO (The Indian Journal of Pediatrics, July 1989, vol. 56, no. 4, pp. 545-548), and in further view of Alexander et al. (US 4,981,844), in further view of Bissbort et al. (US 5,545,670) as applied to the claims 13, 45, 48, 49, 53, 54, 57, 58 and 63, in further view of Gutteridge et al. (US 5,561,164).**

The teachings of Chaiyabutr et al., WHO, Alexander et al. and Bissbort et al. are as applied to claims 6, 13, 42-45, 48, 49, 51, 53, 54, 57, 58 and 63.

Chaiyabutr et al., WHO, Alexander et al. and Bissbort et al. do not teach wherein the composition comprises a pharmaceutical acceptable carrier (claim 50), or is formulated for parenteral administration (claim 59), intradermal administration (claim 60), oral administration (claim 61), or as a tablet (claim 62).

Gutteridge et al. teach a pharmaceutical composition for the treatment of infections that cause diarrhea (see abstract; column 1, line 63; and column 2, line 24). The pharmaceutical formulations include those suitable for oral, topical (including

dermal, buccal and sublingual), rectal and parenteral (including subcutaneous, intradermal, intramuscular and intravenous), administration as well as administration by naso-gastric tube. The formulation may, where appropriate, be conveniently presented in discrete dosage units and may be prepared by any of the methods well known in the art of pharmacy. All methods include the step of bringing into association the active ingredient with liquid carriers or finely divided solid carriers or both and then, if necessary, shaping the product into the desired formulation, including tablets (column 5, lines 40-61).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the combination of Chaiyabutr et al., WHO, Alexander et al. and Bissbort et al. wherein the composition comprises a pharmaceutical acceptable carrier (claim 50), or is formulated for parenteral administration (claim 59), intradermal administration (claim 60), oral administration (claim 61), or as a tablet (claim 62) because effective therapy to treat diarrhea is known in the art to be formulated in the above as taught by Gutteridge et al. Therefore, it is within the skill of the art to formulate pharmaceuticals in the above to deliver therapy to treat diarrhea.

3) Claims 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chaiyabutr et al. (J Med Ass Thailand, Dec 1985, vol. 68, no. 12, pp. 649-53) as applied to claims 6, 42, 43, 44 and 51 above.

The teachings of Chaiyabutr et al. are as applied above to claims 6, 42, 43, 44 and 51.

Chaiyabutr et al. does not teach a composition comprising tacrine or donepezil as the acetylcholine enhancer.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the combination of Chaiyabutr et al. and the acetylcholine enhancer tacrine or donepezil because they are both acetylcholine enhancers. The composition of Chaiyabutr et al. comprises the acetylcholine enhancer oxyphenonium bromide, so using tacrine or donepezil instead of oxyphenonium bromide would within reasonable expectation have the same effect because they are all acetylcholine enhancers.

4) Claims 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chaiyabutr et al. (J Med Ass Thailand, Dec 1985, vol. 68, no. 12, pp. 649-53) as applied to claims 6, 42, 43, 44 and 51 above in view of WHO (The Indian Journal of Pediatrics, July 1989, vol. 56, no. 4, pp. 545-548), and in further view of Alexander et al. (US 4,981,844), in further view of Bissbort et al. (UA 5,545,670) as applied to the claims 13, 45, 48, 49, 53, 54, 57, 58 and 63, in further view of Legakis (WO 95/31199 A1).

The teachings of Chaiyabutr et al., WHO, Alexander et al. and Bissbort et al. are as applied to claims 6, 13, 42-45, 48, 49, 51, 53, 54, 57, 58 and 63.

Chaiyabutr et al., WHO, Alexander et al. and Bissbort et al. do not teach wherein the amount of clioquinol is 5 mg to 250 gm or 10 mg to 50 mg.

Lexakis teaches a method of treating Helicobacter infections which cause gastric diseases administering clioquinol (see abstract, claims 8, 10 and 12) in amounts of 10 to 50 mg (see page 11, lines 27-28).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the combination of Chaiyabutr et al., WHO, Alexander et al. and Bissbort et al. wherein the amount of clioquinol is 5 mg to 250 gm or 10 mg to 50 mg because Lexakis teaches a treatment of infections that are known in the art to cause diarrhea with clioquinol (see abstract, claims 8, 10 and 12) in amounts of 10 to 50 mg (see page 11, lines 27-28). Thus, it is known in the art to treat the infections that cause diarrhea with lower doses than those taught by Chaiyabutr et al. One skilled in the art would be motivated to administer the patient less of a drug than more in order to not over medicate the patient.

5) **Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chaiyabutr et al. (J Med Ass Thailand, Dec 1985, vol. 68, no. 12, pp. 649-53) as applied to claims 6, 42, 43, 44 and 51 above in view of WHO (The Indian Journal of Pediatrics, July 1989, vol. 56, no. 4, pp. 545-548), and in further view of Alexander et al. (US 4,981,844), in further view of Bissbort et al. (UA 5,545,670) as applied to the claims 13, 45, 48, 49, 53, 54, 57, 58 and 63, in further view of Gross et al. (US 3,574,819)**

The teachings of Chaiyabutr et al., WHO, Alexander et al. and Bissbort et al. are as applied to claims 6, 13, 42-45, 48, 49, 51, 53, 54, 57, 58 and 63.

Chaiyabutr et al., WHO, Alexander et al. and Bissbort et al. does not teach the amount of phanquinone is 10 mg to 50 mg (claim 52)

Gross et al. teach a pharmaceutical preparation for treating digestive disorders comprising 4,7-phenanthrolin-5,6-quinone (phanquinone) together with 7-iodo-5-chlor-8-hydroxyquinoline (clioquinol) in the abstract. The amounts of phanquinone can be from 20 to 80 mg (see column 2, lines 3-6) and the amount of clioquinol is from about 80 to 120 mg (see column 1, lines 60-61).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the combination of Chaiyabutr et al., WHO,

Alexander et al. and Bissbort et al. and wherein the amount of phanquinone is 10 mg to 50 mg because of the following teachings: 1) Chaiyabutr et al. teaches an amount of 60 mg of phanquinone; 2) Gross et al. teaches that phanquinone is effective from 20 to 80 mg (see colun 2, lines 3-6). Thus, it is within the normal skill of scientists or artisans to improve upon what is already generally known to provide an effective amount of phanquinone for each patient with the motivation to provide an effective treatment for diarrhea.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. D. C./
Examiner, Art Unit 1617

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617